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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,823	06/01/2005	Akira Kawahara	OMY-0041	7306

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RADER FISHMAN & GRAUER PLLC
LION BUILDING
1233 20TH STREET N.W., SUITE 501
WASHINGTON, DC 20036

EXAMINER	
FOSTER, CHRISTINE E	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/516,823	KAWAHARA ET AL.	
	Examiner	Art Unit	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-19 and 21-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20* is/are rejected.

7)☒ Claim(s) *20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group V, claim 20 in the reply filed on May 22, 2006 is acknowledged. The traversal is on the ground(s) that the Examiner has not correctly applied the standard for unity of invention in that each of Groups I-VII share the same technical feature of "an antibody recognizing vitellogenin" (Applicant's response, p. 1-3).

2. This is not found persuasive because the record as clearly set forth in the previous Office action shows that the technical feature of "an antibody to vitellogenin" cannot be considered to be a *special technical feature* since it does not represent a contribution over the prior art as taught by Palmer et al. (see the previous Office action at p. 2-4). Thus, in accordance with PCT Rule 13.2, which states that unity of invention exists *only when the shared same or corresponding technical feature is a contribution over the prior art*, Groups I-VII were properly shown to lack unity of invention.

Applicant further argues that a search of the entire application could be made without serious burden, and points to MPEP 803. This is not found persuasive because Applicant is referring to the requirement to demonstrate search burden that pertains to applications filed under 35 U.S.C. 111(a) (see MPEP 801). There is no corresponding requirement to demonstrate search burden in applications filed under 35 U.S.C. 371.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-19 and 21-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Specification

4. The disclosure is objected to because of the following informalities: the required section heading "Brief Summary of the Invention" is not present.

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

5. In addition, the specification is objected to because on p. 72, line 22, there is a non-text character (square) in the middle of the word "Schlegel".

6. At p. 30, line 23, "vitellogeninpecific" should be --vitellogenin-specific--.

7. At p. 53, line 4, "Block Ace" should be --BlockAce--.

8. The use of the trademarks "TWEEN", "SEPHADEX", "SEPHAROSE", "BLOCKACE" has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

9. Claim 20 is objected to because of the following informalities: the claim recites "anti-blood serum". It appears that Applicant intends to refer to "antiserum".

10. Claim 20 recites a "polyclonal antibody **of** a frog vitellogenin". To clarify the relationship between the antibody and antigen, the Examiner suggests "polyclonal antibody specific for frog vitellogenin" (see for example the specification at p. 30).

11. Claim 20 recites the step of "isolating as an IgG". For clarity, it is suggested that the claim clearly recite what is being isolated in this step (i.e., the polyclonal antibody).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites the step of "sampling an anti-blood serum". The recitation of "sampling" is vague and indefinite. It is unclear what this step of "sampling" refers to--what is being sampled in the antiserum? It is unclear how the step of "sampling" is involved in preparing the antibody and what such a step would entail.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer et al. ("Vitellogenin as a Biomarker for Xenobiotic Estrogens in an Amphibian Model System" (1988) *Environ. Toxicol. Chem.* **17**, 30-36, Applicant's Information Disclosure Statement of 6/1/05) in view of Dunbar et al. ("Preparation of Polyclonal Antibodies" (1990) *Methods in Enzymology* **182**, 663-670).

Palmer et al. teach a polyclonal antibody against vitellogenin from the African clawed frog (*Xenopus laevis)* (see the abstract; p. 31, left column, the second paragraph; p. 31, the sections "Purification of Xenopus Vitellogenin" and especially "Polyclonal antibody production"; and p. 32-33, "Enzyme-linked immunosorbent assay (ELISA)" and "Evaluation of antisera and immunoassays"). The antibody was prepared by immunizing a mammal (rabbits) with purified frog vitellogenin as an antigen and isolating anti-vitellogenin antiserum from the rabbits.

Palmer et al. do not specifically teach that the polyclonal antibody was isolated as an IgG from the antiserum.

However, Dunbar et al. teach that it is often desirable to partially purify polyclonal antibodies from antiserum prior to use (p. 669-670, "Fractionation of Ig from Serum"). In particular, Dunbar et al. teach DEAE-Sephacel ion-exchange chromatography as well as protein A affinity chromatography as methods to yield the IgG fraction, purified from other immunoglobulin subclasses and most serum proteins.

Therefore, it would have been obvious to one of ordinary skill in the art to isolate the IgG fraction of the polyclonal antibody of Palmer et al. from antiserum because Dunbar et al. teach that such a step is effective in purifying polyclonal antibodies and that such purification is desirable prior to using the antibodies.

Conclusion

17. No claims are allowed.

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kawahara et al. ("Quantitative analysis of protein synthesis altered by estrogen in cultured *Xenopus* liver parenchymal cell" (1981) Develop., Growth and Differ. 23, 599-611), like Palmer et al. above, also teaches anti-vitellogenin antisera prepared from frog vitellogenin (see in particular p. 601, "Immunological identification of vitellogenin").

Simon et al. (US 5,153,117) and Hoyer et al. (US 5,304,496) are also cited for their teaching of purifying the IgG fraction of polyclonal antibodies (see Simon et al. at column 7, lines 22-35 and Hoyer et al. at column 7, lines 23-39).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cfoster

Christine Foster, Ph.D.
Patent Examiner
Art Unit 1641

LONG V. LE 06/14/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600